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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,461	03/02/2001	Esteban Cvitkovich	4512/80212	9636

7590 05/25/2004

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,461	Applicant(s) CVITKOVICH ET AL	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claims 1-11 are presented and represent all of the claims under consideration.

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

The abstract of the disclosure is objected to because the present claims are not directed to "preparation of a medicament". Correction is required. See MPEP § 608.01(b).

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 1 provides for the use of ET743, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by

Drugs Fut.

The reference teaches the administration of a formulation comprising ET-473 for intravenous administration to treat human cancers such as chemoresistant ovarian carcinoma, as well as lung, melanoma and renal cancer.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Izbicka et al., Annals of Oncology.

Izbicka teaches the administration of ET-743 against various human tumors. See Tables 1a and 1b, pages 983 and 984. As required by claim 4, metastatic breast cancer is included in the disclosure. See page 985, column 2, at the end of the first full paragraph. ET-743 may inhibit the growth of some tumors resistant to other drugs. See the last line on page 985 to the first line on page 986.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izbicka et al., Annals of Oncology.

Izbicka teaches the administration of ET-743 against various human tumors. See Tables 1a and 1b, pages 983 and 984. Fifteen tumor types are disclosed. Both one hour and continuous exposure of ET-743 through intravenous administration are disclosed. See page 985, column 2, at the end of the first full paragraph. ET-743 may inhibit the growth of some tumors resistant to other drugs. See the last line on page 985 to the first line on page 986. The claims differ with respect to dosing regimens. However, one skilled in the oncology art would have been motivated to select dosages either between 1000-1500 micrograms/m² over a period of 24 hours, or, 1000-1650 micrograms/m² over a period of 3 hours in view of Izbicka's teaching. Such would have been obvious in the absence of evidence to the contrary because Izbicka recites a maximum tolerated dose of 600 µg/m², as well as one hour exposures and continuous exposures (24 hours). Multiple cycles of 3-4 weeks are conventional chemotherapeutic practices. The determination of safe and effective dosages with the occurrence of minimal adverse effects is a parameter well within the purview of those skilled in the oncology art through no more than routine experimentation.

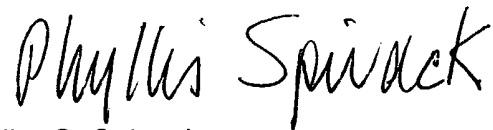
No claim is allowed.

Rinehart et al., U.s. Patent 5,478,932, is cited to show further the state of the art with respect to treatment of sarcoma through administration of ET-743.

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Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 571-272-0585.

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

May 12, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER